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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,596	11/24/2003	Dror Harats	27041	1012

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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,596

Applicant(s)

HARATS ET AL.

Examiner

Robert Shiao

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 05/19/2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This application claims benefit of the provisional application: 60/252,574 with a filing date 11/24, 2000.
2. Claims 1-19 are pending in the application.

Responses to Election/Restriction

3. Applicant's election with traverse without argument of Group I claims 1-8 in the reply filed on May 19, 2005, is acknowledged. Claims 9-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

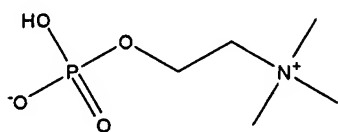
Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter "preventing" and "R₃ is selected from phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl serine, phosphatidyl cardiolipin and phosphatidyl inisitol", "HMGCoA reductase inhibitors", "anti-inflammatory compounds", "analgesics", "growth factors", "toxins", or "tolerizing antigens", which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, see claim 1, line 1, page 67, lines 5-6, and claim 8, lines 3-6. It is noted that phosphatidyl choline is phosphoglycerides having a propylene backbone, and on which two hydrocarbon chains are respectively linked to the first and second carbon of the propylene backbone, and phosphocholine is linked to the third carbon of propylene backbone. Phosphocholine is a moiety having the below formula,



, which is one of moieties of the elected species 1-hexadecyl-2-(5'-oxo-pentanyl)-sn-glycero-3-phosphocholine. Moreover, the limitation of the variable "-O-R₃" of working examples is preferably phosphocholine moiety of phosphatidyl choline, see page 44, Example 1. No limitation of the variable "R₃" is other than phosphocholine moiety (i.e., hydrocarbon chains) is found in the specification. A suggestion to obviate the rejection would be to eliminate the limitation "preventing and/or", and incorporate the limitation of R₃, i.e., -O-R₃ represents phosphocholine, phosphoethanolamine, phosphocardiolipin, or phosphoinositol, in the claims respectively.

6. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the instant methods treating atherosclerosis using compound of formula of claim 1, wherein -O-R₃ represents phosphocholine, or HMGCoA represents statins, does not reasonably provide enablement for a method of preventing atherosclerosis, wherein R₃ represents phosphatidyl choline, in a normal

subject, or, HMGCoA represents other than statins. The specification does not enable any person skilled in the art to which it pertains, with which it is most nearly connected, to use the invention commensurate in scope with these claims, see claim 1, line 1, page 67, lines 5-6, and claim 8, lines 3-6.

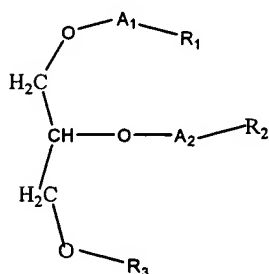
For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claims are drawn to methods of use (i.e., preventing atherosclerosis) using compounds of the formula,



, wherein R₃ is phosphatidyl choline without disclosing specific moiety (i.e., -OR₃ represents phosphocholine).

2) State of the prior art.

The reference Baldo et al. 5,061,626 does not indicate which compounds of instant formula may be useful in the claimed invention. Baldo et al. '239 is pertaining to PAF analogues with various substituents.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The methods of use (i.e., preventing atherosclerosis) of above formula, wherein R_3 is phosphatidyl choline without disclosing specific moiety (i.e., $-OR_3$ represents phosphocholine). Applicant's specification does not enable the public to prepare such a numerous amount of methods of the formula by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The art pertaining to methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R_3 is phosphatidyl choline without disclosing specific moiety (i.e., $-OR_3$ represents phosphocholine), remains highly unpredictable, see claim 1, line 1 and page 67, lines 5-6. Different types of the genus of the formula require various experimental procedures and without guidance that is applicable to all possible "moieties of phosphatidyl choline" or "preventing atherosclerosis", there would be little predictability in the scope of claimed compounds.

5) Amount of direction and guidance provided by the inventor.

The methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R_3 is phosphatidyl choline without disclosing specific moiety (i.e., $-OR_3$ represents phosphocholine), encompasses a vast number of methods. Applicant's

limited guidance does not enable the public to prepare such a numerous amount of "methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R₃ is phosphatidyl choline without disclosing specific moiety (i.e., -OR₃ represents phosphocholine)" in the specification. There is no enablement for "methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R₃ is phosphatidyl choline without disclosing specific moiety (i.e., -OR₃ represents phosphocholine), many of which are neither enabled nor supported in the specification.

6) Existence of working examples.

The methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R₃ is phosphatidyl choline without disclosing specific moiety (i.e., -OR₃ represents phosphocholine), encompasses a vast number of methods. Applicant's limited working examples do not enable the public to prepare such a numerous amount of "methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R₃ is phosphatidyl choline without disclosing specific moiety (i.e., -OR₃ represents phosphocholine)" in the specification. Applicants claim "methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R₃ is phosphatidyl choline without disclosing specific moiety (i.e., -OR₃ represents phosphocholine)", however, the specification provides only limited examples of the instant methods.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R₃ is

phosphatidyl choline without disclosing specific moiety (i.e., -OR₃ represents phosphocholine)".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain "methods of use (i.e., preventing atherosclerosis) using compounds of above formula, wherein R₃ is phosphatidyl choline without disclosing specific moiety (i.e., -OR₃ represents phosphocholine)" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. A suggestion to obviate the rejection would be to eliminate the limitation "preventing and/or", incorporate the limitation of R₃, i.e., -O-R₃ represents phosphocholine, phosphoethanolamine, phosphocardiopin, or phosphoinositol, and incorporate the limitation of HMGCoA reductase inhibitor i.e., statins, in the claims respectively.

Claim Rejections - 35 USC § 102

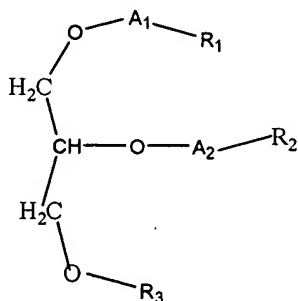
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by (1) Kern et al. publication, *Biochimica et Biophysica Acta* (1998), 1394(1), 33-42, see CAS: 130:50286; (2) Junius et al. US 5,091,527, see CAS: 112:77856; (3) Aono et al. JP 63054386, see CAS: 109:170803; (4) Nitta et al. publication, *Journal of Leukocyte Biology* (1984), 36(4), 493-504, see CAS: 102:4277; (5) Macpherson et al. publication, *Journal of Lipid Mediators* (1992), 5(1), 49-59, also see CAS: 117:68162; (6) Wang et al. publication, *Chemistry and Physics of Lipids* (1990), 55(3), 265-73, also see CAS: 114:40661; (7) Karasawa et al. publication, *Journal of Biochemistry* (Tokyo, Japan) (1991), 110(5), 683-7, also see CAS: 116:39343; (8) Smal et al. publication, *Molecular Immunology* (1989), 26(8), 711-19, also see CAS: 111:192750; (9) Berchtold's publication, *Chemistry and Physics of Lipids* (1981), 28(1), 55-60, also see CAS: 95:42295.

Applicants claim methods of use (i.e., treating atherosclerosis) using compounds of the formula,

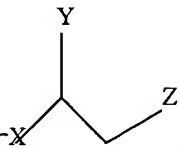


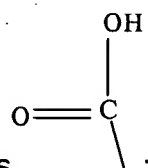
(1): Kern et al. disclose a compound 3,5,9-Trioxa-4-phosphapentacosan-1-aminium, 7-(4-carboxy-1-oxobutoxy)-4-hydroxy-N,N,N-trimethyl-, inner salt, 4-oxide, i.e.,



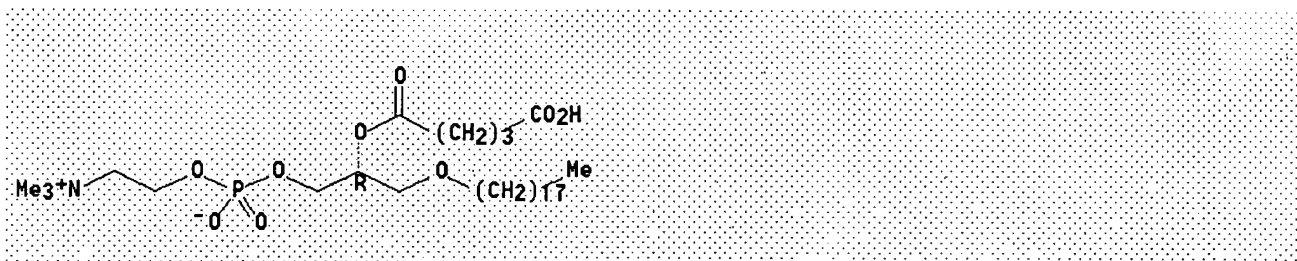
. It clearly

anticipates the claimed compounds, wherein A_1 represents CH_2 , R_1 represents alkyl

chain having 15 carbon atoms, A_2 represents $C=O$, R_2 represents $\text{---}X$ , X represents an alkyl chain having one carbon atom Y represents H, Z

represents  ; $-OR_3$ represents phosphocholine, see RN: 217322-89-9.

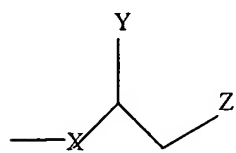
(2): Junius et al. disclose a compound 3,5,9-Trioxa-4-phosphaheptacosan-1-aminium, 7-(4-carboxy-1-oxobutoxy)-4-hydroxy-N,N,N-trimethyl-, inner salt, 4-oxide, i.e.,



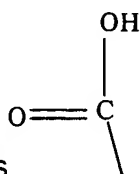
. It clearly anticipates the claimed compounds, wherein A_1 represents CH_2 , R_1

represents alkyl chain having 17 carbon atoms, A_2 represents $C=O$, R_2 represents

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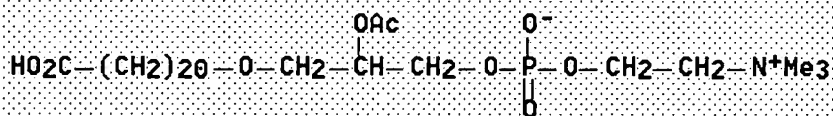


, X represents an alkyl chain having one carbon atom Y represents H, Z

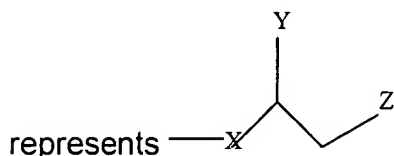


represents ; -OR₃ represents phosphocholine, see RN: 125001-84-5.

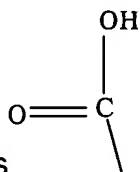
(3): Aono et al. disclose a compound 3,5,9-Trioxa-4-phosphanonacosan-1-aminium, 7-(acetyloxy)-29-carboxy-4-hydroxy-N,N,N-trimethyl-, inner salt, 4-oxide, i.e.,



. It clearly anticipates the claimed compounds, wherein A₁ represents CH₂, R₁

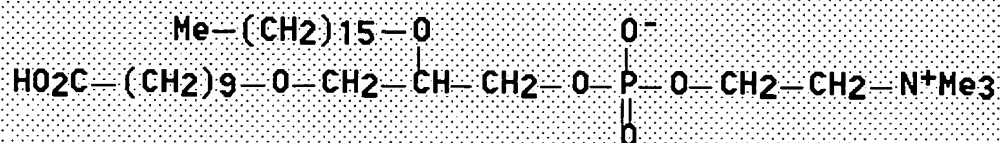


represents , X represents an alkyl chain having 17 carbon atom Y

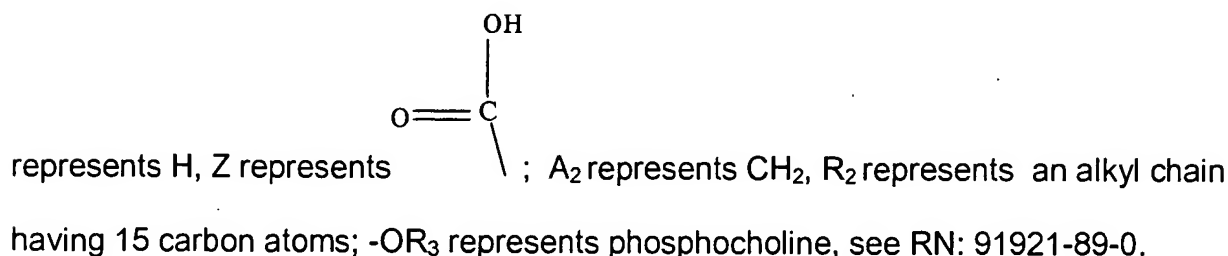


represents H, Z represents ; A₂ represents C=O, R₂ represents an alkyl chain having one carbon atom; -OR₃ represents phosphocholine, see RN: 117045-25-7.

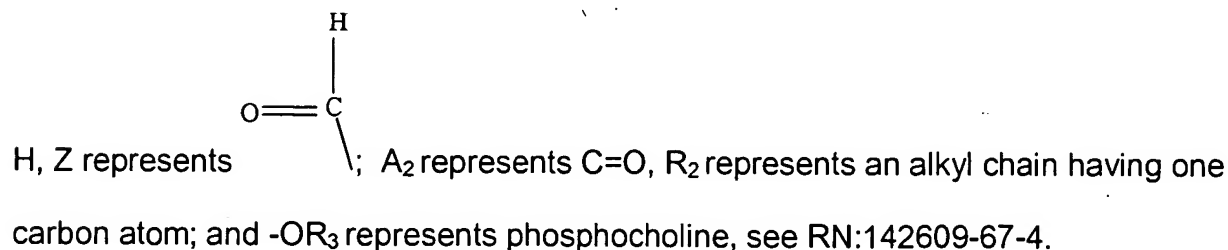
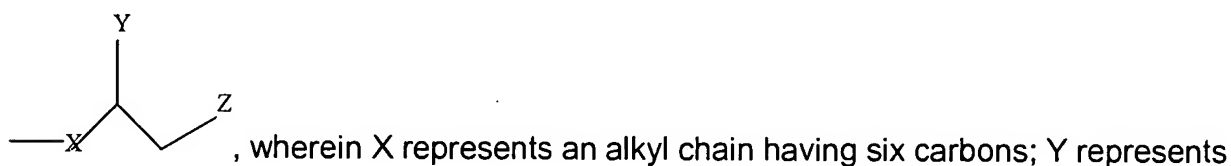
(4): Nitta et al. disclose a compound 3,5,8-Trioxa-4-phosphatetracosan-1-aminium, 7-[[[(9- carboxynonyl)oxy]methyl]-4-hydroxy-N,N,N-trimethyl-, inner salt, 4-oxide, i.e.,



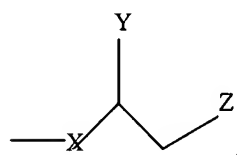
. It clearly anticipates the claimed compounds, wherein A₁ represents CH₂, R₁



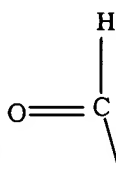
(5): Macpherson et al. disclose a compound 3,5,9-Trioxa-4-phosphanonadecan-1-aminium, 7-(acetyloxy)-4-hydroxy-N, N, N-trimethyl-19-oxo-, inner salt, 4-oxide, clearly anticipates the claimed compounds, wherein A₁ represents CH₂, R₁ represents



(6): Wang et al. disclose a compound 3,5,9-Trioxa-4-phosphaoctadecan-1-aminium, 7-(acetyloxy)-4-hydroxy-N, N, N-trimethyl-18-oxo-, inner salt, 4-oxide, clearly anticipates the claimed compounds, wherein A_1 represents CH_2 , R_1 represents

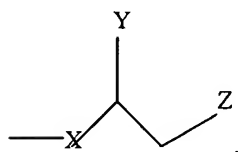


, wherein X represents an alkyl chain having five carbons; Y represents

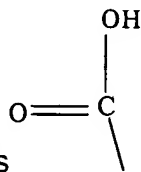


H, Z represents A_2 represents $C=O$, R_2 represents an alkyl chain having one carbon atom; and $-OR_3$ represents phosphocholine, see RN:131418-02-5.

(7): Karasawa et al. disclose a compound 3,5,9-Trioxa-4-phosphatetracosan-1-aminium, 7-(acetyloxy)-24-carboxy-4-hydroxy-N, N, N-trimethyl-, inner salt, 4-oxide, clearly anticipates the claimed compounds, wherein A_1 represents CH_2 , R_1 represents



, wherein X represents an alkyl chain having 12 carbon; Y represents H,

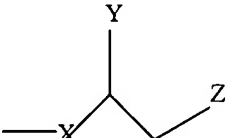


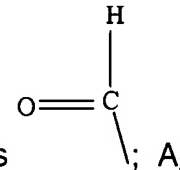
Z represents A_2 represents $C=O$, R_2 represents an alkyl chain having one carbon atom; and $-OR_3$ represents phosphocholine, see RN:129879-41-0.

(8): Smal et al. disclose two compounds 3,5,9-Trioxa-4-phosphapentadecan-1-aminium, 7-(acetyloxy)-4-hydroxy-N, N, N-trimethyl-15-oxo-, inner salt, 4-oxide;

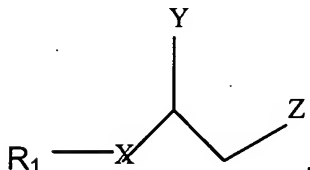
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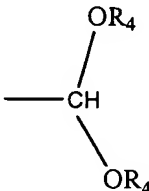
3,5,9-Trioxa-4-phosphaheneicosan-1-aminium, 7-(acetyloxy)-4-hydroxy-N, N, N-trimethyl-21-oxo-, inner salt, 4-oxide; clearly anticipates the claimed compounds,

wherein A_1 represents CH_2 , R_1 represents , wherein X represents an

alkyl chain having two or eight carbons; Y represents H, Z represents ; A_2 represents $\text{C}=\text{O}$, R_2 represents an alkyl chain having one carbon atom; and $-\text{OR}_3$ represents phosphocholine,, see RN:119142-21-1 and RN:123473-54-1.

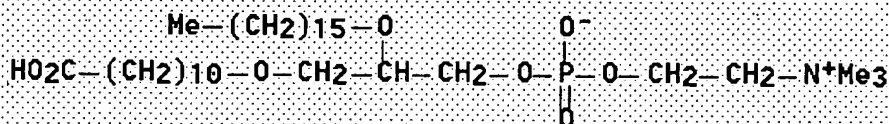
Smal et al. disclose two compounds 2,9,13,15-Tetraoxa-14-phosphaheptadecan-17-aminium, 11-(acetyloxy)-14-hydroxy-3-methoxy-N, N, N-trimethyl-, inner salt, 14-oxide; and 2,15,19,21-Tetraoxa-20-phosphatricosan-23-aminium, 17-(acetyloxy)-20-hydroxy-3-methoxy-N, N, N-trimethyl-, inner salt, 20-oxide, wherein A_1 represents CH_2 ,

, wherein X represents an alkyl chain having two or eight carbons;

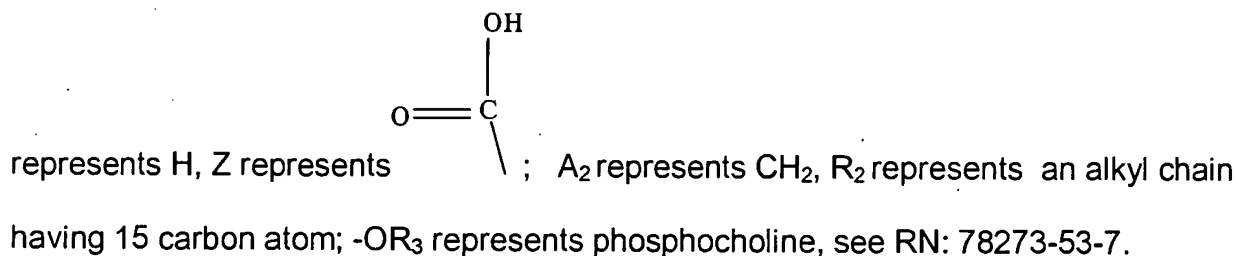
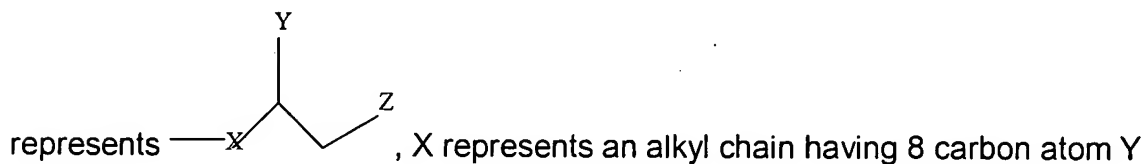
Y represents H, Z represents , R_4 represents methyl; A_2 represents $\text{C}=\text{O}$, R_2 represents an alkyl chain having one carbon atom; and $-\text{OR}_3$ represents phosphocholine, see RN:119142-20-0 and RN:123473-53-0.

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(9): Berchtold disclose a compound 3,5,8-Trioxa-4-phosphatetracosan-1-aminium, 7-[[[(10-carboxydecyl)oxy]methyl]-4-hydroxy-N,N,N-trimethyl-, inner salt, 4-oxide, i.e.,



. It clearly anticipates the claimed compounds, wherein A₁ represents CH₂, R₁



Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

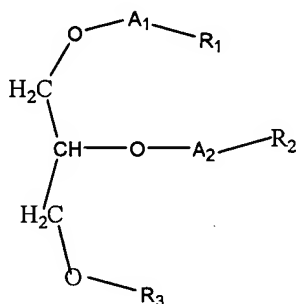
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re

Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

9. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smal et al. publication, Molecular Immunology (1989), 26(8), 711-19, also see CAS: 111:192750.

Applicants claim methods of use (i.e., treating atherosclerosis) using compounds of the formula,



and the instant compounds and methods of use have been found on the pages 26-65 of the specification.

Determination of the scope and content of the prior art (MPEP §2141.01)

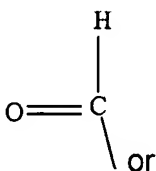
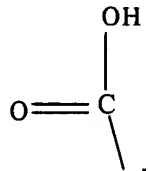
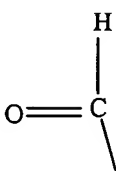
Smal et al. disclose two PAF (platelet activating factor) derivatives compounds 3,5,9-Trioxa-4-phosphapentadecan-1-aminium, 7-(acetyloxy)-4-hydroxy-N, N, N-trimethyl-15-oxo-, inner salt, 4-oxide; and 3,5,9-Trioxa-4-phosphaheneicosan-1-aminium, 7-(acetyloxy)-4-hydroxy-N, N, N-trimethyl-21-oxo-, inner salt, 4-oxide.

Smal et al. compounds are related to heart diseases, i.e., hypertension, bronchoconstriction, see page 711, and page 727, Fig. 3, also see RN:119142-21-1 and RN:123473-54-1 of DN: 111:192750.

Determination of the difference between the prior art and the claims (MPEP

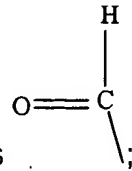
§2141.02)

The difference between the instant claims and Smal et al. is that the

instant variable Z represents  or , while Smal et al. represents  at the same position.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 1-8 prima facie obvious because one would be motivated to employ the compound and inherent teachings of Smal et al. to obtain instant methods of use, i.e., treating cardiovascular disease, wherein X represents an alkyl chain having two or eight carbons ; Y

represents H, Z represents ; A₂ represents C=O, R₂ represents an alkyl chain having one carbon atom; and -OR₃ represents phosphocholine.

The motivation to make the claimed compounds/methods of use derives from the expectation that the instant claimed compounds would possess similar activities, i.e., treating cardiovascular disease, from the known Smal et al. compounds or methods of use to that which is claimed in the reference.

Telephone Inquiry

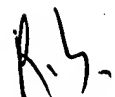
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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July 07, 2005